

PATENT APPLN. NO. 10/786,369  
RESPONSE UNDER 37 C.F.R. § 1.116

PATENT  
FINAL

REMARKS

Claims 29-34 and 38-46, withdrawn from consideration, have been canceled to expedite an allowance of the claims, claims 35 and 37, remaining in the application.

In the Final Action, claims 35 and 37 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office asserts that the specification lacks clear correlation of inhibition of implanted cancer cell growth in animal by sediments of extinguished cancer cell culture produced only by treatment with Yoshixol or Yoshixol 7001 and lacks written descriptive support for the compounds encompassed by formula 3-a useful for the therapy of cancer.

To overcome this rejection, first, claim 35 has been amended to delete the substitution groups (i.e., alkylene, alkyl, polycyclic hydrocarbon, naphthalene, azulene, heptalene, pentalene, thiophene, pyrrole, g-pyran, g-thiopyran, thiazole, imidazole, pyrimidine, indole and quinoline group) identified by the Office as being "diverse with respect to structure and chemical reactivity and specification does not provide any guidance as to what functional groups would be a representative of substitution group hydrogen having similar reactivity." (Final Action, page 7, lines 2-5 from the bottom of the page).

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The amendment to claim 35 deletes only alternative substitution groups and, therefore, does not involve new matter or raise any new issues that would require further search and/or consideration. Entry of the amendment is respectfully requested.

Second, a Declaration under 37 C.F.R. § 1.132 of one of the inventors, Shozo KOYOMA, is submitted herewith in which the anti-cancer effect of Yoshixol-treated cancer cells is compared to that of cancer cells treated with surfactant (lysis buffer) and that of mechanically destroyed (homogenized) cancer cells. The results show that Yoshixol-treated cell sediment has a materially stronger anti-cancer effect than cell lysate and cell homogenate.

The showing of the 132 declaration is believed to establish that only cancer cell sediment that has been treated with Yoshixol and Yoshixol 7001 have component(s) which, when injected in mice, provide(s) inhibition of implanted cancer cell growth. The anti-cancer effect of Yoshixol-treated cancer cell sediment is shown in the specification, and the effect is further confirmed by using the desired controls. Those skilled in the art can conclude with certainty that Yoshixol treated cells provide inhibition of cancer cell growth in an animal, because a clear relationship between Yoshixol treated cells and the desired immunotherapy exists.

Removal of the 35 U.S.C. § 112, first paragraph, rejection and

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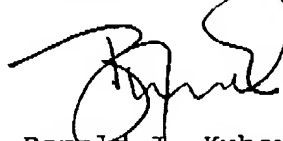
a notice of allowability of the claims are respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated June 25, 2009.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,  
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Attachment: Declaration under 37 C.F.R. § 1.132 of Shozo KOYAMA